IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, and ENDO PAR INNOVATION COMPANY, LLC,	)	
Plaintiffs,	)	C.A. No. 18-823-CFC-JLH
v.	)	[redacted]
EAGLE PHARMACEUTICALS INC.,	)	
Defendant.	)	

PLAINTIFFS' OPENING BRIEF IN SUPPORT OF ITS EMERGENCY MOTION FOR A PRELIMINARY INJUNCTION PENDING APPEAL

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INTRODUCTION

The FDA just granted Eagle approval to sell its generic version of Par's VASOSTRICT® product ("Vasostrict"), which Eagle is planning to launch soon. That planned launch, if permitted, would inflict massive harm that threatens Par's ability to continue as a going concern and could render Par's appeal of the Court's non-infringement ruling a moot exercise. Accordingly, Par moves for a preliminary injunction pending appeal, to preserve the status quo and give the Federal Circuit an opportunity to address an important question of law before an Eagle launch that would critically injure Par.

This is a Hatch-Waxman Act patent infringement case in which Par alleges that Eagle has infringed two patents relating to Vasostrict. As Par candidly told the Court during opening arguments at trial, there is tension in the law between the treatment of a paper ANDA filing and the use of real-world evidence. In that limited respect, the Court agreed with Par, noting in its trial opinion that the governing Federal Circuit authorities seemingly cannot be reconciled:

> I have spent more hours than my caseload affords trying without success to reconcile these passages with the unequivocal holdings from the Federal Circuit cases.

D.I. 300 at 27 n.2.

Ultimately, the Court rejected Par's position on how the case law could be synthesized, adopted a rule that gave almost exclusive primacy to the ANDA itself, and entered a judgment of non-infringement against Par.

Par has appealed, and the central issue on appeal is the conundrum the Court identified in its trial opinion—reconciling the seeming conflict between two lines of Federal Circuit authority. In short order, the Federal Circuit will tell us all what the law is, but in the interim, Par asks the Court to maintain the status quo. The stakes could not be higher for Par, with [redacted] of its income, and potentially its ability to continue as a going concern, dependent on the outcome. The harm from allowing generic sales before the Federal Circuit has had a chance to weigh-in to clarify the law would be catastrophic and irreparable.

This case meets the four-factor balancing standard for the issuance of injunctive relief pending appeal:

First, to satisfy the likelihood of success factor, Par need only demonstrate that its appeal presents a "substantial legal question" regarding liability. By itself, Footnote 2 of the Court's decision shows there is such a question here: an apparent conflict in Federal Circuit case law that needs to be reconciled. Moreover, the Court made two first-impression rulings: (a) a first of its kind interpretation of the FDA stability specification regulation; and (b) a decision to rely on an ANDA filer's representation that it would follow an "optimized" process and not use the

full scope of the FDA authorization it had applied for. Each of these issues raises a significant, unresolved legal question.

Second, Eagle's planned at-risk launch,[1] if unchecked, would inflict massive and irreparable harm on Plaintiffs, including significant impairment of their ability to fund ongoing research and development (R&D), to support planned new product launches, to fund employee salaries and other overhead expenses at current levels, to defend and resolve the ongoing country-wide opioid litigations, and to pay debt obligations and obtain additional capital to support business operations.

Third, the harm to Par would vastly exceed the consequences to Eagle of maintaining the status quo. Granting the injunction would leave Eagle in the same position it was in yesterday, before the FDA approved its ANDA. At most, Eagle will temporarily forego some profit, which can be remedied. Indeed, Par will post an appeal bond in an amount sufficient to cover any anticipated financial harm Eagle might suffer.

Finally, the public interest also favors maintaining the status quo. There is a significant public interest in protecting Par's intellectual property rights and

[1] Eagle's launch would be a "at-risk" because it would occur before giving the Federal Circuit time to hear Par's appeal, such that it would be "at-risk" of a potential adverse appellate decision.

investment in R&D—and this interest outweighs any benefit Eagle attributes to its generic product, including potentially lower prices.

FACTUAL AND PROCEDURAL BACKGROUND

The Court conducted the trial in this matter in July 2021. Prior to trial Eagle stipulated that its product would meet each limitation of the asserted patent claims, except the limitations relating to pH. Tr. 121:21-24; 251:15-24; 253:5-16. The Court found that Eagle did not infringe and, in view thereof, did not address Eagle's invalidity defenses. D.I. 300. Par filed a timely notice of appeal. D.I. 307.

Yesterday, Eagle finally obtained final FDA approval. *See* Ex. A to Bradley Decl.[2] Eagle and its CEO have stated that the company plans to launch its generic product soon,[3] and Eagle has refused Par's requests that it agree to hold off doing so pending appeal. Eagle's planned launch, if unchecked, would inflict immediate and irreparable harm on Par and its parent company (Endo) to such a degree that it would jeopardize their ability to continue as going concerns and could trigger a

[2] The FDA also denied a Citizen's Petition Par had filed relating to the FDA's review of Eagle's ANDA, relying in part on some of the findings of fact made the Court made in its trial opinion.

[3] *See id.*; D.I. 312 at 1; https://investor.eagleus.com/press-releases/news-details/2021/Eagle-Pharmaceuticals-Announces-FDA-Maintains-Prioritization-of-ANDA-for-Vasopressin/default.aspx.

bankruptcy filing. A detailed discussion of these harms can be found in the Declarations of Endo CFO Mark Bradley ("Bradley Decl.") and economist John Jarosz ("Jarosz Decl.") being filed in support of Par's motion.

ARGUMENT

I. LEGAL STANDARDS

Pursuant to Rule 62(d), a party seeking an injunction pending appeal has the burden to show (1) that it is reasonably likely to prevail on appeal; (2) that it is likely to suffer irreparable harm in the absence of relief; (3) that the balance of equities favors an injunction; and (4) that an injunction would serve the public interest. *K.A. ex rel. Ayers v. Pocono Mountain Sch. Dist.*, 710 F.3d 99, 105 (3d Cir. 2013); *see also Republic of the Philippines v. Westinghouse Elec. Corp.*, 949 F.2d 653, 658 (3d Cir. 1991). In weighing these factors, courts apply a "sliding-scale," whereby the greater the balance of harms weighs in the movants' favor, the less heavily its likelihood of success must also weigh in its favor, and vice versa. *In re Revel AC, Inc.*, 802 F.3d 558, 569-70 (3d Cir. 2015); *Standard Havens Prods. v. Gencor Indus.*, 897 F.2d 511, 513 (Fed. Cir. 1990); *Jacobson v. Lee*, 1993 WL 262664, at *3 (Fed. Cir. 1993). Indeed, this Court has granted injunctions pending appeal even if a party failed to make a "strong showing" of its likelihood of success, where other factors strongly favored a stay. *See Advanced Med. Optics, Inc. v. Alcon Labs, Inc.*, 2005 WL 3454283, at *11 (D. Del. Dec. 6, 2005).

II. THE COURT SHOULD ENJOIN EAGLE'S AT-RISK LAUNCH PENDING APPEAL

Applying these standards in ANDA cases, this Court and others have granted preliminary injunctions pending appeal to prevent the immediate irreparable harm that branded pharmaceutical companies inevitably suffer upon entry of generic competition. *See, e.g., Eli Lilly & Co. v. Actavis Elizabeth LLC*, 2010 WL 3374123, at *1 (Fed. Cir. Aug. 26, 2010); *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 2011 WL 1980610, at *3 (D. Del. May 20, 2011) ("In every ANDA case there is a likelihood of irreparable harm for the name brand manufacturer as the generics have a ready-made market to flood as soon as they receive approval to release their products."); Hr'g Tr. at 88-89, *Galderma v. Teva*, Civ. No. 17-1783-RGA, D.I. 296 (D. Del. Nov. 5, 2019) (granting preliminary injunction pending appeal); Order at 1-2, *Galderma v. Teva*, Civ. No. 17-1783-RGA, D.I. 299 (Nov. 5, 2019) (granting preliminary injunction pending appeal); *Par Pharm., Inc. v. TWi Pharm., Inc.*, 2014 WL 3956024, at *4 (D. Md. Aug. 12, 2014) ("The court is persuaded that Par would suffer irreparable harm should TWi launch its product before the Federal Circuit has decided the appeal" because Par demonstrated that generic launch would cause branded division to shut down as well as irreversible price erosion and revenue losses).

Here, each factor weighs strongly in favor of granting an injunction to prevent the immediate and irreparable harm that Eagle's planned at-risk launch, if

unchecked, would inflict on Par before the Federal Circuit has an opportunity to decide Par's appeal.

A. Par has a Reasonable Chance of Prevailing on Appeal

To satisfy the likelihood of success factor, Par need only show "a reasonable chance, or probability, of winning" which need not be greater than 50%. *Singer Mgmt. Consultants, Inc. v. Milgram*, 650 F.3d 223, 229 (3d Cir. 2011) (en banc); *see also In re Revel*, 802 F.3d at 570-71 (collecting cases and stating that "strong showing" means "significantly better than negligible but not greater than 50%"). One way of demonstrating a likelihood of success is by demonstrating that a "substantial legal question" exists regarding liability. *See Standard Havens Prods.*, 897 F.2d at 514; *see also E.I. DuPont de Nemours & Co. v. Phillips Petroleum Co.*, 835 F.2d 277, 278 (Fed. Cir. 1987).

Par's infringement case presented a novel legal question regarding the use of real-world evidence, and the Court found the pertinent Federal Circuit jurisprudence to be irreconcilable. D.I. 300 at 27 n.2. The Court also issued a ruling of first impression with respect to the importance of FDA regulations on a stability specification and credited Eagle's statement that it would avoid using the full scope of its FDA authorization. Each of these reflects a substantial legal question warranting an order maintaining the status quo pending appeal.

1. This Case Raises Substantial Legal Questions Regarding the Standard for ANDA Infringement

In its non-infringement ruling, the Court found an irreconcilable conflict in two strands of Federal Circuit case law regarding how courts should evaluate real-world data concerning the manner in which a generic product *will perform* when sold, versus what the pieces of paper submitted with the ANDA say about how the product *should perform* once approved. That issue constitutes a substantial question for appeal.

On one hand, the Federal Circuit says that where ANDA product specifications directly address the disputed issue of infringement, those specifications control the infringement inquiry. D.I. 300 at 21-22 (citing *Sunovion Pharms., Inc. v. Teva Pharms. USA, Inc.*, 731 F.3d 1271, 1278 (Fed. Cir. 2013); *Abbott Lab'ys v. TorPharm, Inc.*, 300 F.3d 1367, 1373 (Fed. Cir. 2002); *Bayer AG v. Elan Pharmaceutical Research Corp.*, 212 F.3d 1241 (Fed. Cir. 2000); *In re Brimonidine Patent Litig.*, 643 F.3d 1366, 1378 (Fed. Cir. 2011); *Ferring B.V. v. Watson Lab'ys, Inc-Fla.*, 764 F.3d 1401, 1409 (Fed. Cir. 2014)).

On the other hand, the Federal Circuit also says that infringement can be proven based on real-world data generated on sample ANDA products. D.I. 300 at 27 n.2 (citing *Tyco Group LP v. Mutual Pharm. Co.*, 762 F.3d 1338 (Fed. Cir. 2014); *Abbott Labs.*, 300 F.3d at 1373). *See also Bayer AG v. Biovail Corp.*, 279 F.3d 1340, 1346-47 (Fed. Cir. 2002).

Bayer v. Biovail illustrates the principle. There, the ANDA specification required that the active ingredient have a "specific surface area" (SSA) above the claimed range. 279 F.3d at 1342-43. The Federal Circuit nevertheless reversed summary judgment of non-infringement based on evidence that the active ingredient could meet the ANDA specification initially, but later fall within the claimed range once incorporated into finished products. *Id.* at 1346-47. This was despite a prior ruling in an earlier case involving a related ANDA seeking approval for a product with a different dosage strength (30 mg), in which the Federal Circuit found non-infringement based on the ANDA specifications alone. In the latter case, involving a 60 mg product, the Federal Circuit held that "[e]ven assuming Elan strictly follows its 60 mg ANDA … in making a commercial tablet, Professor Antonietti's declaration raises a legitimate question as to whether Elan will likely make a 60 mg product that literally infringes Bayer's '466 patent upon approval of the ANDA." *Id*; *see also Tyco*, 762 F.3d at 1344 ("it is not unreasonable for a patent owner to allege infringement under section 271(e)(2)(A) if the patent owner has evidence that the as-marketed commercial ANDA product will infringe, even though the hypothetical product specified in the ANDA could not infringe").

The Court found that these authorities could not be reconciled even after great effort. That is the definition of a substantial legal question.

2. The Court's Interpretation of the FDA Stability Specification Regulations Raises a Question of First Impression

In granting primacy to the written ANDA and downgrading real-world evidence, the Court issued a ruling of first impression on the interpretation of the regulations governing FDA stability specifications. This too presents a substantial issue for appeal.

The Court found, as the parties had agreed, that a stability specification embodies the "tests and acceptance criteria that a drug product ***should*** meet throughout its shelf-life." D.I. 300 at 10 (emphasis added). The Court further found that "Eagle's ANDA product cannot [] lawfully be distributed for use and would not be approved for distribution by the FDA unless, *at all periods during the product's shelf life*, the product's pH is between 3.4 and 3.6." *Id.* at 10-11 (emphasis added). However, there is no support for that finding in the trial record or FDA regulations. Whereas release testing must be conducted on each batch prior to release, and a confirmed out-of-specification test result will preclude release of the batch, post-approval stability testing is conducted only on an exceedingly small sample of vials collected from a small number of commercial batches. *See*, Tr. 219:22-220:18, Tr. 299:12-23. There was no evidence that by approving an ANDA, the FDA has determined that every batch of generic product will successfully satisfy the stability specification at all times. To the contrary, if

the FDA were able to make that determination in advance, there would be no need for any post-sale stability testing. Tr. 219:22-220:18.[4]

In any event, Par presented extensive real-world data demonstrating that a proportion of products made within the upper-end of Eagle's release specification will drift above the stability specification and into infringing territory, including:

- Batch SVA001, rose into infringing range during its shelf-life, the root cause of which was that it was released with a pH of 3.64, which given the variable pH drift of Eagle's products allowed it to drift above 3.6. *E.g.*, PTX-1435 at 9; PTX-53 at AMRIVAS0114547; Tr. 220:19-23, 221:15-222:8, 224:4-226:12; 227:2-16.

- Eagle's statistical analysis of its registration batches concluded that they exhibited a statistically significant increase in pH and that SVA001 and SVA003 would be expected to have pH values within the claimed range during their shelf-lives. *E.g.*, PTX-1435 at 9-10, Fig. 1; Tr. 236:7-237:5, 237:16-238:17, 317:20-320:7.

- Eagle did not amend its release specification to preclude release of a batch with a pH at the upper limit of its pH specification. *See* Tr. 223:17-23.

- Eagle's supposedly "optimized batches" exhibit upward drifts in pH from in-process testing to release (by as much as 0.07 pH units) and post-release increases of as much 0.06 pH units. Of the

[4] As Dr. Kirsch testified, only the first three commercial batches and one batch per year thereafter will be tested during their shelf-life. Tr. 219:22-220:18. And even if that limited testing catches an out-of-specification result, there is no evidence that FDA would require a recall or order any other measure that would mitigate infringing activity. Rather, an out-of-specification result during post-approval stability testing triggers a requirement to submit a Field Alert Report, which may or may not lead to a recall and/or to changes in the product specifications. *See, e.g.*, 21 C.F.R. 314.81(b)(1)(ii).

> 45 pH measurements of Eagle's "optimized" products after release when stored in refrigeration, 32 of them were higher than the release value. DDX-7-4. Eagle's expert confirmed that these pH increases were representative of what we can expect from future commercial batches. Tr. 461:8-12, 474:7-12 (Park); PTX-1442. And simple math demonstrates that some batches released at 3.60-3.64 would be expected to drift into infringing territory.

A critical legal question, therefore, is whether it was proper for the Court to "reject Par's attempt to use testing data" to support a conclusion that some portion of the products Eagle would be authorized to sell upon FDA-approval of its ANDA would be likely, in the real-world, to drift above Eagle's stability pH specification and infringe Par's patents. D.I. 300 at 26-27. Par respectfully submits that the law requires consideration of that evidence, even if strict conformity with the stability specification would indicate non-infringement. *See, e.g., Biovail*, 279 F.3d at 1346-47; *Tyco*, 762 F.3d at 1344.

3. The Court's Decision to Rely on the Middle of the Release Specification, Rather than its Outer Bounds, Raises a Substantial Question for Appeal

The cases the Court relied on for the proposition that ANDA specifications control the infringement analysis make clear that courts must evaluate the ***full scope*** of what the ANDA applicant has asked the FDA to approve. *Sunovion*, 731 F.3d at 1278. Accordingly, Par was not required to prove that Eagle's ANDA product would always infringe. *See, e.g.*, *Adams Respiratory Therapeutics, Inc. v.*

Perrigo Co., 616 F.3d 1283, 1287 (Fed. Cir. 2010).[5] Promises—like Eagle's—that its "manufacturing guidelines will keep it outside the scope of the claims" will not suffice if "it has asked the FDA to approve, and hopes to receive from the FDA, approval to market a product within the scope of the issued claims." *Sunovion*, 731 F.3d at 1278.

Here, Par's argument was not that Eagle would neglect to follow its revised manufacturing process, as some of the Court's findings seem to suggest. D.I. 300 at 17-19, 28. Rather, it was and is that products made at the upper-limits of Eagle's in-process and release specifications would be likely to infringe. The data the Court relied on in finding no infringement were for batches made in the lower-end to middle of Eagle's in-process and release specifications. As Appendix Table 1 to the Court's decision illustrates, ***none*** of the limited batches made with Eagle's "optimized" process were made at the upper-end of either the in-process or release specification, which would allow finished products to be sold with a measured

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[5] *See also Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1318 (Fed. Cir. 2009) (affirming infringement where jury could reasonably conclude that "more likely than not one person somewhere in the United States had performed the claimed method"); *BroadCom Corp v. Emulex Corp.*, 732 F.3d 1325, 1333 (Fed. Cir. 2013) ("It is well settled that an accused device that sometimes, but not always, embodies a claim nonetheless infringes.") (internal quotation marks omitted); *Omega Patents, LLC v. CalAmp Corp.*, 920 F.3d 1337, 1344 (Fed. Cir. 2019) (tacit admission that infringement would occur some amount less than 5% of the time supports finding of infringement).

release pH as high as pH 3.64.[6] For instance, the highest post-filtration pH value for Eagle's "optimized" batches was 3.50, although Eagle's specifications permit final in-process (post-filtration) pH values of up to 3.54.

The correct legal question is as follows: ***If*** Eagle were to make batches at the upper-end of the in-process and release specifications, would there likely be infringement? The answer on the evidence at trial was an unequivocal yes. Indeed, the Court agreed that the pH of Eagle's product varied even when made using its "optimized" process. S*ee* D.I. 300 at 16-17. In its appeal, Par will argue that by concluding that "the pH measurements for Eagle's ANDA product will be between 3.45 (that is, 3.50 minus 0.05) and 3.57 (that is, 3.52 plus 0.05) at the time of their release and over their shelf lives," D.I. 300 at 17, 27, the Court failed to account for the full scope of what Eagle has asked the FDA to approve—a batch released at pH 3.64. That is another substantial legal question favoring entry of the requested injunction.

B. Par Will Suffer Irreparable Harm If the Injunction Is Not Granted

As detailed in the Bradley and Jarosz Declarations, any premature launch-at-risk by Eagle before the Federal Circuit has time to resolve the important legal

[6] In addition, none of those batches had full 24 month stability data available, and three of those six batches only had six months of stability data available.

issues noted above, if unchecked, would inflict wide-ranging, multi-faceted, long-term, corporate-wide harm on Par and Endo that raises substantial doubt about their ability to continue as going concerns and could trigger a bankruptcy filing. Par would lose [redacted] and the onset of generic competition would lead to substantial, irreversible price erosion. Bradley Decl. ¶¶ 22-29; Jarosz Decl. ¶¶ 80-92; 111-114. The resulting precipitous loss of revenue would, in turn, have dramatic ripple effects, including impairment of Par's and Endo's investments in R&D and planned sales and marketing efforts, their ability to fund employee salaries and other overhead expenses, Endo's ability to defend and resolve the ongoing opioid litigations, and their ability to pay down debt and their cost of capital. Bradley Decl. ¶¶ 30-44; Jarosz Decl. ¶¶ 115-134. These impacts are inter-related and intertwined, in that negative impacts in any one of these areas will have compounding ripple effects that negatively affect the others and radiate throughout Par, Endo and its other subsidiaries, such that the full extent of these ripple effects would be both incalculable and irreversible. Bradley Decl. ¶ 41; Jarosz Decl. ¶¶ 100-114, 130, 134, 159.

Courts recognize that branded pharmaceutical companies suffer these types of harms upon the onset of generic competition and that these harms are irreparable and support entry of preliminary injunctive relief. *See, e.g., Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1361-62, 1371 (Fed. Cir. 2008); *Sanofi-Synthelabo v.*

Apotex, Inc., 470 F.3d 1368, 1382-84 (Fed. Cir. 2006); *AstraZeneca LP v. Apotex*, 633 F.3d 1042, 1063 (Fed. Cir. 2010). These harms are particularly acute for Par and Endo, given their fragile financial condition.

Sales by Eagle [redacted] will necessarily represent lost sales by Par, and "[t]here can be no doubt that [this] loss of market share, sales, and business opportunities constitutes irreparable harm." *Edwards Lifesciences AG v. CoreValve, Inc.*, 2014 WL 1493187, at *5 (D. Del. Apr. 15, 2014); *see also Ortho McNeil Pharm., Inc. v. Barr Labs., Inc.*, 2009 WL 2182665, at *9-10 (D.N.J. July 22, 2019).

Courts have further recognized that price erosion "is most likely to occur in cases like this one, in which no generic competitors have yet entered the marketplace." *Ortho McNeil*, 2009 WL 2182665, at *10; *see also Sanofi-Synthelabo*, 470 F.3d at 1382-83 (generic launch would force the branded company to "offer discounted rates and price concessions" to third-party payors and that it would be "nearly impossible" to restore pre-launch pricing).

Courts have also found the related, incalculable ripple effects from such losses of revenues to be irreparable harm supporting injunctive relief, including

[7] [redacted]

where lost revenues "required [plaintiff] to reduce its research and development activities." *Bio-Technology Gen. Corp. v. Genentech, Inc.*, 80 F.3d 1553, 1556 (Fed. Cir. 1996). In *Par v. TWi*, Par presented evidence that sales of the product at issue (Megace ES) represented 50% of the revenues of its branded division, Strativa, and that the profits generated from Megace went back into funding Strativa's operations with respect to other products. 2014 WL 3956024, at *3. The court found that given how quickly generic drugs overtake the market, "Strativa would quickly lose an essential part of its funding." *Id*. Based on that, in combination with the irreversible effects of price erosion and lost goodwill, the court found irreparable harm pending Par's appeal to the Federal Circuit sufficient to support entry of an injunction. *Id.* at *3-4. *See also Abbott Labs.*, 544 F.3d at 1362 ("loss of [] research and development support constitute[s] irreparable harm"); *Eli Lilly & Co. v. Teva Pharm. USA, Inc.*, 609 F. Supp. 2d 786, 812 (S.D. Ind. 2009) (irreparable harm from "a scaling back of investment in research and development which otherwise would not have occurred").

Finally, the damages Par would suffer in the event of an unchecked Eagle launch-at-risk would likely exceed Eagle's ability to pay, such that to the extent Par's damages would be calculable, any damage award in Par's favor should Par prevail in its appeal would be a pyrrhic victory, with Eagle unable to compensate Par for the massive damage it inflicted. Jarosz Decl., ¶¶ 135-139.

C. The Balance of the Hardships Favors Granting the Requested Injunction

Because "[Par] will suffer irreparable harm absent an injunction, the balance of equities weighs strongly in [Par's] favor." *See Nevro v. Stimware Techs., Inc.*, No. 19-325, 2019 WL 3322368, at *16 (D. Del. July 24, 2019). Moreover, the hardship Par would suffer far exceeds the consequences to Eagle of preserving the ex ante status quo.

First, the harms inflicted on Par—e.g., price erosion, lost R&D opportunities, impaired promotion of new and early-stage products, etc.—will be catastrophic and irreversible, to the point of potentially putting them it bankruptcy. Bradley Decl. ¶¶ 41-44; Jarosz Decl. ¶¶ 115-134, 148. And while an injunction might postpone Eagle's revenues temporarily, that "does not rise to the level necessary to overcome the loss of exclusivity experienced by a patent owner due to infringing conduct." *Pfizer v. Teva Pharm., USA, Inc.*, 429 F.3d 1364, 1382 (Fed. Cir. 2005). An injunction will merely "leave [Eagle] in the same position as it was in before the injunction was granted, i.e., excluded from the [vasopressin] market." *Impax Labs, Inc. v. Aventis Pharm., Inc.*, 235 F. Supp. 2d 390, 396 (D. Del. 2002).

Second, Par's hardships will be incalculable. Eagle's launch-at-risk, if unchecked, would cause multi-faceted, inter-related corporate-wide harms on Par and Endo to the point of threatening their ability to continue as going concerns long enough to benefit from any favorable appellate ruling. Bradley Decl. ¶¶ 21,

35, 38, 41, 44; Jarosz Decl. ¶¶ 101-109, 111-114, 123, 130, 134. In contrast, any potential loss of profits Eagle would experience due to an injunction "are quantifiable, more so and more easily than the harms [Par] will suffer." *Research Found. of the State Univ. of N.Y. v. Mylan Pharm. Inc.*, 723 F. Supp. 2d 638, 660-62 (D. Del. 2010). And the potential harm to Eagle is delayed profits, from being forced to wait some number of months until the Federal Circuit decides the important questions at the heart of Par's appeal, not profits that are forever lost.

Third, Par's hardships, though unquantifiable, will be enormous. Vasostrict generates approximately [redacted] million per year in revenues and contributes nearly [redacted] of Endo's company-wide EBITDA. Bradley Decl. ¶¶ 7, 31; Jarosz Decl. ¶ 39. Those revenues are critical to Par's and Endo's ability to fund and support their overall business operations. Par projects that absent an injunction, the total loss in annual revenues would be in excess of [redacted] million within one year of an Eagle launch-at-risk. The harm resulting from a precipitous drop in revenues of that magnitude would be particularly acute in the circumstances presented here because Endo and Par are in a precarious financial condition.

Eagle, in contrast, stands only to lose possible future revenues, and in view of the anticipated erosion in price [redacted] the potential future profits Eagle may lose is only a fraction of the [redacted]

million in annual revenues that Par would lose. Thus, as in *Par v. TWi*, "[Eagle] would not face the same kind of structural harm if the status quo is maintained that Par would suffer if it is not. Instead, [Eagle] will suffer delayed revenue that it can recover through damages." 2014 WL 3956024, at *5; *see also Novartis Pharm. Corp. v. Accord Healthcare Inc.*, 2019 WL 2588450, at *6.

Finally, the requested injunction, if granted, will be "on terms for bond or other terms that secure [Eagle's] rights." Fed. R. Civ. P. 62(d). The bond should be set for an amount sufficient to cover the lost profits Eagle may suffer during the pendency of the appeal. *See, e.g., Par v. TWi*, 2014 WL 3956024, at *6; Order at 1-2, *Butamax Advanced Biofuels LLC v. Gevo, Inc.*, No. 11-54 (D. Del. Aug 7, 2012), D.I. 461. Thus, Eagle will be compensated should it be determined that the injunction was improvidently entered.

D. An Injunction Is in the Public Interest

The public interest favors an injunction. There is a "significant public interest in encouraging investment in drug development and protecting the exclusionary rights conveyed in valid pharmaceutical patents." *Abbott Labs.*, 544 F.3d at 1362-63 (internal quotation marks omitted). Any public benefit Eagle attributes to prematurely launching its generic product while Par's appeal is pending is outweighed by "the public interest in recognizing [Par's] patent rights, and more generally promoting continued, large-scale investment in research and

development of new pharmaceuticals." *Research Found.*, 723 F. Supp. 2d at 663. Indeed, in the ANDA context, "[s]elling a lower priced product does not justify infringing a patent." *Pfizer*, 429 F.3d at 1382. Though the Hatch-Waxman framework "seek[s] to make low-cost generic drugs available to the public, it does not do so by entirely eliminating the exclusionary rights conveyed by pharmaceutical patents." *Id*. Thus, the public interest in allowing Par's appeal to be heard outweighs the temporary delay in availability of potentially cheaper drugs.

Moreover, Par has reliably supplied the full market for vasopressin products, such that any patient that could be treated with Eagle's ANDA product can be treated with Vasostrict. Bradley Decl. ¶ 10; Jarosz Decl. ¶ 156. Therefore, an injunction will not injure the public's interest in "hav[ing] as wide a variety of treatment options as is possible." *Nevro*, 2019 WL 3322368, at *16.

CONCLUSION

The Court should enjoin Eagle from selling its ANDA product pending appeal.

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Respectfully submitted,

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CERTIFICATION OF COMPLIANCE

The foregoing document complies with the type-volume limitation of this Court's March 2, 2020 form Scheduling Order for All Cases. The text of this brief, including footnotes, was prepared in Times New Roman, 14 point. According to the word processing system used to prepare it, the brief contains 4,998 words, excluding the case caption, signature block, table of contents and table of authorities.

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